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REMARKS

Claims 2, 6-12 and 39, and 43-55 are pending in the present application. Claims 19 – 38 are withdrawn as being directed to a non-elected invention. Claims 3-5 and 40-42 have been canceled and claims 2 and 39 have been amended to recite that the respiratory dispersion comprises a plurality of perforated microstructures that are substantially permeated by the suspension medium wherein more than 30% of the average particle volume of the perforated microstructures is permeated by said suspension medium. Claims 52-55 have been newly added. Support for this amendment is found throughout the specification, for example at page 17, line 23 – page 18, line 11, page 21, lines 5-16, and page 22, lines 1-7.. Applicant respectfully submits that no new matter is introduced by this amendment and requests entry thereof.

Claims 2-12 and 39-51 have been rejected under 35 U.S.C. § 103 as being unpatentable over Faithfull et al. in view of Hanes et al. In response, claims 2 and 39 have been amended to recite that the respiratory dispersion comprises a plurality of perforated microstructures that are substantially permeated by the suspension medium wherein wherein more than 30% of the average particle volume of the perforated microstructures is permeated by said suspension medium. Such shell volumes typically contribute little to the virtual particle density that is overwhelmingly dictated by the suspension medium found therein. This control of particle morphology according to the present invention provides a unique solution to problems associated with providing stable suspensions for pulmonary delivery. Applicant respectfully submits that the rejection has been overcome and should be withdrawn for the reasons that follow.

Faithfull et al. is directed to an apparatus and method for closed circuit ventilation therapy. As disclosed at column 16, lines 27-55, the ventilation system may further comprise a nebulizer 98 communicating with the inspiratory ventilating conduit 50. The nebulizer may be used to deliver liquid medium such as fluorochemicals heated above body temperature to the ventilating gas in the form of a vapor to assist in gas exchange and oxygenation. As seen at column 17, lines 5-29, Faithfull et al. teaches performing partial liquid ventilation (PLV) comprising the administration of very low doses of fluorochemicals (0.01 ml/kg or less) sufficient to form a thin coating on a portion of the lung to reduce surface tension at the alveolar air-liquid interface thereby facilitating lung expansion and increasing oxygen availability.

Alternatively, Faithfull et al. suggests the use of a nebulizer to administer fluorochemical or respiratory agents to the gas flow path for the closed-circuit ventilation system (22: 26-35, 23: 35-42).

However, Faithfull et al. is silent as to stability problems associated with suspensions for nebulization. Thus, Faithfull et al. in no way discloses or suggests the unique approach of the claimed invention wherein particle morphology of perforated microstructures is controlled in order to provide stable suspensions in a fluorochemical medium for nebulization. Specifically, Faithfull et al. does not disclose or suggest a plurality of perforated microstructures comprising at least one bioactive agent suspended in and substantially permeated by a fluorochemical continuous phase wherein more than 30% of the average particle volume of the perforated microstructures is permeated by said suspension medium as claimed by Applicant.

Hanes et al. does not satisfy these deficiencies of Faithfull et al. Although Hanes et al. is directed to porous particles for aerosol drug delivery, the disclosure therein is silent as to the use of fluorochemicals as a suspension medium as well as problems associated with particle suspensions for aerosol delivery and suspension stability in such a suspension medium. With no recognition of the problem addressed by the present invention, Hanes et al. provides absolutely no guidance to one of ordinary skill in the art seeking to address problems related to suspension stability. In particular, Hanes et al. does not disclose or suggest a plurality of perforated microstructures comprising at least one bioactive agent suspended in and substantially permeated by a fluorochemical continuous phase wherein more than 30% of the average particle volume of the perforated microstructures is permeated by said suspension medium as claimed by Applicant. Thus, Applicant respectfully submits that the rejection of claims 2, 6-12 and 39, and 43-51 has been overcome and should be withdrawn.

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CONCLUSION

Applicants believe that all the pending claims are presently in condition for allowance. However, the Examiner is invited to telephone the undersigned attorney at the number below if it is believed that this will expedite prosecution of the present application.

Respectfully submitted,

Dated: 9/15/00

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